REMARKS

Claims 1-36 are pending. Claims 12, 13, 23, 24, 35 and 36 have been cancelled. Following entry of the amendment, claims 1-11, 14-22 and 25-34 will be under examination. Claims 1, 13, 14 and 28 have been amended. Support for the amendment can be found throughout the application as filed and in cancelled claims 12, 23, 24, 35 and 36. Accordingly, the amendment does not raise an issue of new matter and entry thereof is respectfully requested. Applicants have reviewed the rejections set forth in the Office Action mailed August 7, 2006, and respectfully traverse all grounds for the reasons that follow.

Rejections Under 35 U.S.C. § 102

Claims 1-2, 5, 7-8, 10-13, 28-29, 32 and 34-36 stand rejected under 35 U.S.C. § 102(b) as anticipated by Walt et al., WO 98/40726, (Walt et al. '726) allegedly because Walt et al. '726 describe an array composition having discrete sites and first and second subpopulations of microspheres each having a plurality of different target analytes. The first and second pluralities allegedly constitute antibodies and antigens and are described in Figure 3 and Example 1. Walt et al. also is alleged to describe microspheres distributed on the surface of an array composition at page 7, lines 5- 15 and in Figures 5 and 7.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). Therefore, the Office must show that the single reference cited as anticipatory art describes elements as claimed in order to establish a *prima facie* case of anticipation. Applicants respectfully submit that such a showing is lacking.

Claim 1 is directed to an array composition having a substrate with a surface comprising discrete sites, and a population of microspheres having at least a first and second subpopulation where the first subpopulation includes a plurality of different target analytes having sequences from a first individual and the second subpopulation includes a plurality of different target analytes having sequences from a second individual. Each plurality of different target analytes

are covalently attached to each microsphere. Claim 28 is directed to the population of microspheres having the claimed subpopulations. The claimed invention is patentably distinct from Walt et al. `726 because the cited figure and passages fail to support at least two subpopulations of microspheres where the microspheres of each subpopulation each contain a plurality of different covalently attached target analytes having sequences from different individuals.

Figure 3 is a diagram illustrating microspheres with different chemical functionalities and encoded descriptions of the functionalities (see, for example, page 8, lines 18-21). Target analytes are patentably distinct from the chemical functionalities of Walt et al. `726. For example, Walt et al. `726 describe a chemical functionality to be:

> In common with the prior art, the microsphere 10 is given a chemical functionality 12 , which is typically applied to the microsphere's surface. The chemical functionality is designed so that in the presence of the analyte (s) to which it is targeted, an optical signature of the microsphere, possibly including region surrounding it, is changed.

Walt et al. `726 at page 9, lines 20-25.

In contrast, the application defines the claimed term "target analyte" to be:

> The present invention is directed to the detection of patient sample components or target analytes. By "patient sample components" or "target analytes" or grammatical equivalents herein is meant any molecule in the sample which is to be detected, with proteins and nucleic acids being preferred, and nucleic acids being particularly preferred.

Id. at page 8, paragraph [027] (emphasis added).

Therefore, a target analyte is not anticipated by a chemical functionality because the former refers to a molecule in a sample which is to be detected whereas the latter refers to a moiety that produces an optical signature when bound by target.

The passage cited at page 27, lines 9-16 (Example 2) refers to the subpopulations having different chemical functionalities. As with Figure 3, this passage also fails to support at least two subpopulations of microspheres where each subpopulation each contains a plurality of different target analytes from a different individual because it refers to the chemical functionality.

Therefore, the invention as claimed is patentably distinct from the Office's citation of chemical functionalities corresponding to antibodies obtained from different sources because, as described above, the claims recite a plurality of different target analytes from a different individual attached to a different subpopultation. Accordingly, this ground of rejection is moot and it's withdrawal is respectfully requested.

Claims 1-2, 5-29 and 32-36 stand rejected under 35 U.S.C. § 102(e) as anticipated by Walt et al., U.S. Patent No. 6,327,410, (Walt et al. `410) allegedly because Walt et al.`410 describe an array composition having discrete sites and first and second subpopulations of microspheres each having a plurality of different target analytes. With respect to claims 1 and 28, the Walt et al. `410 patent is related to the Walt et al. `726 application and the Office also cites to Figure 3 and a passage for allegedly describing first and second pluralities constituting antibodies and antigens and microspheres distributed on the surface of an array. With respect to claim 14, Walt et al., `410 is alleged to describe sub-bundles corresponding to discrete sites and different bioactive agents corresponding to a plurality of different target analytes.

Figure 3 in Walt et al. `410 is identical to Figure 3 in Walt et al. `726 as is the cited passage at column 27, lines 30-60 in Walt et al. `410 is compared to Example 2 in Walt et al. `726. Applicants have above shown the invention of claims 1 and 28 to be patentably distinct over this support cited by the Office. Claim 14 also contains the elements of cancelled claims 12, 13, 23, 24, 35 and 36 included in claims 1 and 28. The description of the referenced subpopulations in Walt et al. `410 does not read on the claimed subpopulations where a first claimed subpopulation contains a plurality of different target analytes having sequences from a first individual and the second subpopulation contains a plurality of different target analytes having sequences from a second individual, wherein the pluralities of target analytes are covalently attached to each of the microspheres. Therefore, claims 1, 14, 28 and their dependents are patentably distinct over the Office's citations in Walt et al. `410 and withdrawal of this ground of rejection is respectfully requested.

Claims 1-36 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Chee et al., U.S. Patent No. 6,355,431. The Office alleges that Chee et al. describe an array composition having discrete sites and first and second subpopulations of microspheres where each

microsphere has a plurality of different target analytes. All elements of claim 14 also are allegedly described by Chee et al.

While not conceding that Chee et al. `431 constitutes an invention by another, Applicants respectfully point out that as with Walt et al. `726 and Walt et al. `410, the claimed invention is patentably distinct over Chee et al. `431 because the cited passage similarly does not support at least two subpopulations where a first subpopulation includes having a plurality of different target analytes having sequences from a first individual and a second subpopulation having a plurality of different target analytes having sequences from a second individual, wherein the plurality of different target analytes are covalently attached to each of the microspheres.

Chee et al. `431 may describe a plurality of target analytes but does not describe a plurality of different target analytes covalently attached to a microsphere. In particular, the passages relied upon by the Examiner does not describe a plurality of different target analytes attached covalently to a microsphere because the cited passage is directed to the design of probes. For example, Chee et al. describes that:

> [P]robes can be made using the techniques disclose herein to detect target sequences such as the gene for nonpolyposis colon cancer, the BRCAl breast cancer gene, P53, which is a gene associated with a variety of cancers, the Apo E4 gene that indicates a greater risk of Alzheimer's disease, allowing for easy presymptomatic screening of patients, mutations in the cystic fibrosis gene, cytochome p450s or any of the others well known in the art.

Id., col. 56, lines 23-32.

Although the passage above describes several target sequences to which probes can be made, nothing in the above passage describes the attachment of two or more target analytes obtained from different individuals to microspheres. Similarly, other passages cited by the Office also do not describe the attachment of a plurality of different target analytes having sequences from a first individual to a first subpopulation of microspheres and the attachment of a plurality of different target analytes having sequences from a second individual to a second subpopulation of microspheres. Because Chee et al. `431 does not describe the attachment of different target analytes from different individuals each to different subpopulations of

microspheres, the claimed invention is patentably distinct and withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 3, 4, 30 and 31 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Walt et al., the `410 patent and Dower et al., U.S. Patent No. 5,770,358. The Office alleges that Walt et al. `410 describe an array substrate having discrete sites and at least first and second subpopulations of microspheres having a plurality different target analytes as set forth previously. The Office acknowledges that Walt et al. fail to describe an array including a nucleic acid identifier binding ligand, but further alleges that such components constitute oligo-tags as described by Dower et al. The Office concludes that because Dower et al. allegedly describe the use of oligo-tags for improved library production and identification it would have been obvious to modify the microspheres of Walt et al. `410 with the oligo-tags encoding a bioactive agent for the expected benefit of facilitating production and screening of bioactive agents as further described by Dower et al.

To establish a *prima facie* case of obviousness, the Office must show that the prior art would have taught or suggested the claimed invention to one of ordinary skill in the art and that it could have been carried out with a reasonable likelihood of success when viewed in the light of the prior art. *Brown & Williamson Tobacco v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000), *accord In re Royka*, 180 USPQ 580 (C.C.P.A. 1974) (to establish *prima facie* obviousness, all claim limitations must be taught or suggested by the prior art); M.P.E.P. §2143.03.

Claims 3 and 30 are directed to an array where the microspheres of each subpopulation has identifier binding ligands. Claims 4 and 31 further recites that the identifier binding ligands are nucleic acids.

The Office again relies on the same figure and passage in Walt et al. `410 cited under the § 102(e) rejection for allegedly describing all elements of the base claims 1 and 28. However, as shown previously, the support relied on by the Office is deficient because the base claims are directed to at least two subpopulations where a first subpopulation includes a plurality of

different target analytes having sequences from a first individual and a second subpopulation includes a plurality of different target analytes having sequences from a second individual wherein the plurality of different target analytes are covalently attached to each of the microspheres. The description of oligo-tags is cited for allegedly describing the elements claimed in the dependent claims and therefore cannot teach or suggest the claimed at least two subpopulations each having a plurality of different target analytes. Absent some teaching, suggestion or motivation to arrive at the claimed at least two subpopulations each having a plurality of different target analytes, the combination of Walt et al. `410 and Dower et al. cannot render the invention obvious because all elements are neither taught or suggested. Accordingly, the Office has failed to establish a *prima facie* case of obviousness and withdrawal of this ground of rejection is respectfully requested.

Double Patenting

Claims 1-36 stand rejected for allegedly being unpatentable under obvious-type double patenting over claims 21-35 of Chee et al., U.S. Patent No. 6,355,431 (Chee et al. `410). The Office alleges that both sets of claims are directed to a composition of microsphere populations on a substrate, but differ in that the patent claims recite microspheres having capture probes whereas the instant claims "define" the capture probes as analytes, which can be proteins or nucleic acids as set forth in the dependent claims. The Office concludes that nucleic acids and proteins are therefore obvious over the genus of capture probes.

Claims 1-36 stand rejected for allegedly being unpatentable under obvious-type double patenting over claims 1-18 of Chee et al., U.S. Patent No. 6,544,732 (Chee et al. `732). The Office alleges that both sets of claims are directed to a composition of microsphere populations on a substrate, but differ in that the patent claims recite the microspheres as nanocrystals, but that the instant claims are generic. The Office further alleges that Chee et al. `732 describes the claimed nanocrystals as having two analytes, concluding that the instant claims are unpatentable.

Claims 1-36 stand rejected for allegedly being unpatentable under obvious-type double patenting over claims 1-30 of Chee et al., U.S. Patent No. 6,429,027 (Chee et al. `027). The Office alleges that both sets of claims are directed to a composition of microsphere populations on a substrate, but differ in the arrangement of claim elements and that the instant claims recite

microspheres having two different analytes. The Office further alleges that Chee et al. `027 describes microspheres having two analytes, concluding the instant claims to be unpatentable.

Claims 1-5 and 28-31 stand rejected for allegedly being unpatentable under obvious-type double patenting over claim 14 of Chee et al., U.S. Patent No. 6,620,584 (Chee et al. `584). The Office alleges that both sets of claims are directed to a composition of microsphere populations on a substrate, but differ in the terminology used to define the molecules of the microspheres. In support, the Office alleges that the instant claims recite microspheres having two analytes alleged to be a nucleic acid and nucleic acid identifier, but that the patent describes microspheres as having a primer and decoding sequence.

Applicants respectfully submit that until such time that the claims in the instant application are in condition for allowance the issue of obvious-type double patenting is not ripe because the instant claims may change over the course of prosecution. Therefore, Applicants respectfully defer responding to the above grounds of rejection until prosecution on the merits has been completed and the full scope of allowable subject matter been determined. At that time, Applicants will respond by distinguishing argument or by electing to file a terminal disclaimer.

Claims 1-36 stand provisionally rejected for allegedly being unpatentable under obvious-type double patenting over claims 38, 40-47, 52-54 and 58-62 over copending application serial no. 09/189,543. The Office alleges that the conflicting claims differ only in the arrangement of elements. Applicants respectfully defer this provisional ground of rejection until such time as there is an indication of allowable subject matter in either or both applications.

CONCLUSION

In light of the Amendments and Remarks herein, Applicants submit that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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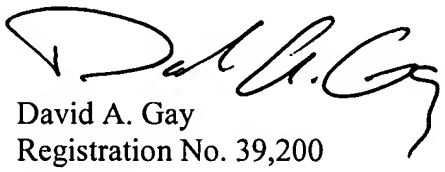

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